

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

V.

Arthrex, Inc.

a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

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**SUBSTITUTE MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S
AND PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION

In 2001, defendant Arthrex, Inc. (“Arthrex”) introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5. The new suture was more than twice as strong as the sutures conventionally used in orthopedic surgery. Ex. 2 at 8. The key ingredient of FiberWire, a “braided suture,” is ultra high molecular weight polyethylene (“UHMWPE”), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1.¹ Arthrex’s FiberWire suture was so new and revolutionary that it spawned a new category of suture called “high-strength” suture. Ex. 2 at 2; Ex. 4 at 146:7-14. Arthrex sells FiberWire separately, and it also includes FiberWire as a component of some of its suture anchors.

After seeing the impact of Arthrex’s FiberWire product, plaintiff DePuy Mitek, Inc. (“DePuy Mitek”) realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5. DePuy Mitek’s original idea was to introduce a “me too” suture that mimicked Arthrex’s FiberWire product. Ex. 5. Eventually, in late 2004, DePuy Mitek introduced its own high strength suture called Orthocord. Ex. 6. DePuy Mitek, however, was not content just to compete in the market. It searched its files to see if it owned some patent that it could assert against Arthrex. Although DePuy Mitek owned no such patents, it located a patent owned by Ethicon, Inc., a sister company that is a part of the Johnson & Johnson empire, and arranged to have the patent assigned to DePuy Mitek to assert it against Arthrex. Ex. 7.

This patent, U.S. Patent No. 5,314,446 (“the ‘446 patent”) (Ex. 8), resulted from a research effort by Ethicon in the late 1980’s and early 1990’s. The ‘446 patent is a paper patent; neither Ethicon nor DePuy Mitek has made a single commercial product under that patent. Ex. 9 at 9-10. Even in the laboratory, Ethicon did not build a sterilized surgical suture that falls within the claims of the patent before the filing date of the ‘446 patent. Ex. 10 at 345:7-10. Despite this

¹ The UHMWPE is braided together with a polyester known as PET.

enormous failure, DePuy Mitek now claims it is entitled to tens of millions of dollars in damages for infringement of this paper patent.

DePuy Mitek's effort to show infringement is a classic example of trying to fit a square peg into a round hole. Unlike Arthrex's FiberWire product, the '446 patent has nothing to do with a high strength suture. Quite to the contrary, the '446 patent, as explained in the specification, involves a combination of materials where a highly pliable and lubricious, but weak, material is added to a stronger material to improve the pliability and handleability aspects of the suture without appreciably sacrificing strength. Ex. 8 at col. 2, ll. 31-37, 62-66; col. 6, ll. 7-8. Even though the resulting suture would be weaker than conventional sutures, the pliability and handling advantages from adding the weak and pliable material outweighs any loss of strength.

Notwithstanding the teachings of the patent, DePuy Mitek asserts that FiberWire infringes. One of the highly pliable and lubricious, but weak, materials identified in the specification is polyethylene, denoted in the claims as "PE." According to DePuy Mitek, the claim term "PE" should be construed to include UHMWPE. The undisputed evidence, however, shows that UHMWPE is extraordinarily strong and a very stiff (non-pliable) material. Ex. 11 at ¶ 56; Ex. 12 at 306:20-307:4. As explained in more detail in the accompanying *Markman* brief ("*Markman Br.*"), DePuy Mitek can only make this argument by putting on blinders and ignoring the patent specification as well as the fundamental differences (e.g., function, molecular weight and molecular structure) between UHMWPE and the long known general purpose PE which had been used in sutures and other materials for decades. Ex. 13 at col. 11, l. 26. In sum, the term PE should properly be construed to exclude UHMWPE and accordingly, there is no infringement.

There is a second, independent reason why there is no infringement. The claims of the '446 patent all include the transitional phrase "consisting essentially of." As in all patent claims, the accused device must meet each and every limitation of the claim. But unlike many patent claims, there is no infringement of a "consisting essentially of" claim if the accused product includes additional ingredients that materially affect the "basic and novel characteristics" of the claimed invention. Here, Arthrex's FiberWire suture includes a coating. Ex. 14. The undisputed evidence in this case, including Ethicon's patents, a patent of DePuy Mitek's expert and the testimony of every relevant witness in this case, is that such coatings are added to sutures to improve the handleability aspects of the suture, especially the "knot tie down" characteristics of the suture. The inclusion of the coating on FiberWire is the death knell to any infringement claim. The stated purpose of the '446 patent was to improve the handleability aspects of the suture. Accordingly, the Arthrex coating affects the basic and novel characteristics of the claimed invention and thus, there is no infringement.²

Apart from the infringement inquiry, the claims of the '446 patent are invalid, particularly if the term "PE" is construed to include UHMWPE. As we show below, the prior art Chesterfield patent, U.S. Patent No. 5,318,575 ("the '575 patent") (Ex. 15), anticipates the claims of the '446 patent because every limitation of the claims is disclosed in that prior art patent (if the term "PE" is construed to include UHMWPE). DePuy Mitek's principal contention seems to be that the '575 patent is not prior art because Ethicon actually reduced its invention to practice before the filing date of that patent. The undisputed evidence, however, belies DePuy Mitek's contention. Ethicon built only a braid (which itself had significant problems), but never

² Arthrex has several other non-infringement arguments, but the above-identified arguments are its principal non-infringement contentions.

built a sterilized suture as required by the claims of the '446 patent. Accordingly, the '575 patent anticipates the claims of the '446 patent.³

II. STATEMENT OF FACTS

A. THE RELEVANT COMPANIES

Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. Ex. 16. FiberWire is one such product. Pearsalls, a United Kingdom company, is a braid manufacturer. Pearsalls manufactures braids that eventually become FiberWire suture. DePuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17. Ethicon, also a Johnson & Johnson company, makes and sells suture and was the original owner of the '446 patent. Ex. 18

B. ETHICON'S DEVELOPMENT WORK

Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at. 103:23-104:17. At the time, the standard braided suture was a product called Ethibond, a suture made entirely of PET polyester which was braided to form the suture. Ex. 4 at 135:4-7.

Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

³ There are other prior art combinations that render the asserted claims of the '446 patent invalid for obviousness pursuant to 35 U.S.C. § 103, and the '446 patent is invalid for failing to meet the written description and enablement requirements of 35 U.S.C. § 112. These issues are not raised by this motion for summary judgment. Similarly, Ethicon committed inequitable conduct during the prosecution of the '446 patent which renders the patent unenforceable. This issue also is not raised by this motion.

In early 1989, Dr. Steckel built and tested several braids, although he did not build a sterilized suture, as set forth in the claims of the '446 patent. Ex. 19 at 225:5-8.⁴ Ethicon never built a sterilized suture before the filing date of the '446 patent. Ex.10 at 346:7-10. The braids that Dr. Steckel tested were made of PTFE (commonly known as Teflon) and PET (the polyester material used in Ethibond). Ex. 21 at DMI 2635-38. PTFE is a relatively weak substance, but is lubricious and quite pliable. PET, on the other hand, is a strong substance which gives the suture acceptable strength to avoid breakage. Ex. 8 at col. 4, ll. 33-40. While the resulting braid was not as strong as the all-PET control braid, Dr. Steckel observed that the increases in pliability (resulting from the lubricious PTFE) outweighed the loss of strength (caused by mixing the PET with the weaker PTFE). Ex. 8 at col. 8, ll. 36-49. Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down *even without a coating.*" Ex. 21 at DMI 2666. [Emphasis added.]

C. THE '446 SPECIFICATION AND PROSECUTION HISTORY

Three years after Dr. Steckel tested the braids, Ethicon filed the patent application that lead to the '446 patent. Ex. 8 at cover page. A full explanation of the '446 patent specification and prosecution history is included in the accompanying Markman brief (*see Markman Br.* at 2 - 6) and is summarized here as it relates to this motion. The specification teaches several things. First, lubricious yarns are too weak to use alone; that is, the suture would break. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 50-54; Table. Second, the lubricious yarns are highly pliable, that is, they are very easy to bend. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 11-14; Table. Third, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly sacrificing the overall braid strength. Ex. 8 at

⁴ Even here, the braids had considerable problems of "core popping," a problem exacerbated by the difficulties presented by attempting to braid together two different materials. More than a year later, Ethicon observed that the problem had not been solved. Ex. 20. There is no evidence that the problems were ever solved. Ex. 19 at 251:24-252:5.

col. 2, ll. 31-37; ll. 62-66; col. 4, ll. 11-40; col. 6, ll. 7-8. Fourth, while adding coating to a braid is helpful for knot tie down (a handleability characteristic), it creates problems with pliability (as well as added costs). The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used. Ex. 8 at col. 6, ll. 5-17.

The pertinent aspects of the prosecution history can be summarized as follows. As originally filed, the application included claims directed toward “braids” and others directed toward “sutures.” Ex. 22 at 18-20. In response to the Examiner’s assertion that “braid” claims and “suture” claims were different, Ethicon agreed only to prosecute the suture claims. Ex. 23 at 3. In response to a rejection of the claims based on the U.K. patent application to Burgess (“the Burgess application”), Ethicon argued that the qualities of UHMWPE would lead to a poor suture, a clear assertion that Ethicon did not believe that UHMWPE was a material that fell within the patent claims. Ex. 24 at 2-4. In addition, the claims were amended during prosecution to limit significantly the scope of the claims. The transitional phrase “comprising” was amended to “consisting essentially of,” a significantly narrower claim. Ex. 25 at 1. The claims were also narrowed by abandoning the requirement that the suture may be made of two “dissimilar yarns” and instead requiring that the two yarns be from a two lists of specified materials (one from each list). Ex. 25 at 1.

In the claims, seven polymers are identified as the yarns in the first group, of which “PE” is one. As explained in the specification, these materials are lubricious and highly pliable, but are too weak to be used alone. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 9-32, 50-54; Table. Three materials, PET, nylon and aramid, are identified in the second group. According to the specification, these materials are added to strengthen the suture. Ex. 8 at col. 4, ll. 33-40. Notably, the term PE is never associated with the “strength” yarns.

D. ARTHREX'S DEVELOPMENT OF FIBERWIRE

In the late 1990's, Arthrex investigated the development of a new suture product.⁵ Its motivation was to develop a suture much stronger than existing sutures in the market, one which would be less likely to break when used in orthopedic surgery. Ex. 26 at 44:13-46:9. The original idea was to make a braided suture entirely of UHMWPE, a material known for its incredible high strength. Ex. 26 at 44:13-46:9. While the prototypes met the strength criteria, there were some problems. The suture was too stiff, that is, it lacked pliability, and was difficult to use. Ex. 12 at 306:20-307:4. In addition, while the knots were strong and did not break, the knots had a tendency to slip, making it difficult to secure the knot. Ex. 26 at 46:7-9. The solution was to add PET (the polyester that was used in existing sutures) to the suture braid. The PET was added to provide better flexibility to the suture and to improve the knot security of the suture. Ex. 26 at 68:25-69:21. FiberWire also adds a coating to improve the ability for the knot to slide down the suture and other handleability aspects of the suture. Ex. 14.⁶ Arthrex introduced FiberWire as a stand alone product in August 2001 and eventually began offering FiberWire as an option on most of its suture anchor products. Ex. 27.⁷

III. ARGUMENT

A. STANDARDS FOR SUMMARY JUDGMENT

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a

⁵ At the time, Arthrex did not sell suture as a separate product. It did attach sutures, which it bought from an outside vendor, to the suture anchors that it sold.

⁶ As an added benefit, the coating improves the strength of the knot and the pliability of the suture.

⁷ Arthrex also sells variants of FiberWire, called TigerWire and FiberStick. For the purposes of this motion, the differences between the products is not relevant. Accordingly, the term "FiberWire" in this motion includes FiberWire and its variants.

matter of law. *Q-Pharma, Inc. v. Andrews Jergens Co.*, 360 F.3d 1295, 1299-1300 (Fed. Cir. 2004). The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor. *Id.*

The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc.*, 299 F.Supp.2d 348, 357 (D. Del. 1994) (citing to *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). If the nonmoving party fails to make a sufficient showing of an essential element of its case with respect to which it has the burden of proof, then the moving party is entitled to judgment as a matter of law. *Id.* (citing to *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). In other words, the court must grant summary judgment if the party responding to the motion fails to make a sufficient showing on an essential element of his case with respect to which he has the burden of proof. *Id.* at 357.

B. FIBERWIRE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '446 PATENT

To establish infringement, the plaintiff must show that the accused product has each and every limitation of the asserted claim either literally or by the doctrine of equivalents. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004). If even a single limitation is missing in the accused product, there is no infringement.

MicroStrategy, Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005). Claim 1, cited in full below,⁸ is an independent claim. The other asserted claims, claims 2, 8, 9 and 12,

⁸ Claim 1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

are dependent claims, that is, they include all the limitations of the independent claim (here claim 1) plus additional limitations. Since the two infringement defenses presented in this motion relate to limitations in the independent claim, they also relate to limitations in the dependent claims.

There are at least two reasons why there is no infringement of the asserted claims. First, the FiberWire product does not have “PE,” as that term should be construed within the patent. Second, the addition of coating to the FiberWire product eliminates any possibility of infringement because coating affects the basic and novel characteristics of the ‘446 patent.

1. The UHMWPE in FiberWire is not a yarn from the first set from the group consisting of PTPE, FEP, PFA PVDF, PETFE, PP AND PE
 - a. There is no literal infringement

The infringement inquiry is a two part process. First, the claim terms must be properly construed and second, a determination must be made whether the accused device has the properly construed limitations. *Dynacore Holdings*, 363 F.3d at 1273. There is no dispute that FiberWire contains UHMWPE. It is DePuy Mitek’s position that UHMWPE constitutes “PE” and thus, the “yarn from the first set” limitation is met. But as we show in our *Markman* brief, the proper construction of “PE” excludes UHMWPE. *See Markman Br.* at 10-16. Should the Court agree, then there is no dispute that FiberWire does not contain any of the identified “yarn[s] from the first set” and accordingly, there is no literal infringement of the asserted claims.

- b. There is no infringement under the doctrine of equivalents

DePuy Mitek contends that even if this Court construes the term “PE” to exclude UHMWPE, there is still infringement under the doctrine of equivalents. Infringement by

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid, and c) optionally a core.

equivalents is a limited doctrine designed to prevent “[o]ne who seeks to pirate an invention [by making] minor variations to conceal and shelter the piracy.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950). Application of the doctrine of equivalents should be the exception, not the rule because, if the doctrine becomes simply the second prong of every infringement charge, claims will cease to serve their intended notice purpose. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed Cir. 1991). Accordingly, infringement by equivalents can only be found if the differences are insubstantial. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997).

The doctrine of equivalents is further limited by the “all elements” rule. This means that equivalents must be applied to individual elements of the claim rather than to the invention as a whole. *Id.* at 18.⁹ Thus, the question is whether the differences between UHMWPE and the first set of yarns is insubstantial. Unless that test is met, there can be no equivalents.

The undisputed facts show that UHMWPE is not equivalent to the materials identified in the first set of yarns. Indeed, for the same reasons that UHMWPE does not fall within the meaning of PE, UHMWPE cannot be considered an equivalent. The first set of yarns constitute lubricious yarns included in the braid “to improve overall pliability” of the suture. Ex. 8 at col. 4, ll. 12-13. A braid made solely of such lubricating yarns is described as “highly pliable.” Ex. 8 at col. 2, ll. 23-24. UHMWPE is stiff (Ex. 12 at 306:20-307:4) and as DePuy Mitek’s expert admits, a braid made of only UHMWPE is too stiff (Ex. 11 at ¶ 56) – the polar opposite of what is described in the ‘446 patent.

⁹ The doctrine of equivalents is further limited by prosecution history estoppel which, except under limited circumstances, prevents a finding of equivalents if the claim limitation was amended. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003). Here, the first set of yarns limitation was added by amendment, so prosecution history estoppel precludes a finding of equivalents. This issue, however, is not presented by this motion.

Likewise, the admitted purpose of using UHMWPE in FiberWire is to add strength to the braid (Ex. 11 at ¶ 56; Ex. 28 at 290:19-25). In the '446 patents, the purpose of the first set of yarns is to improve pliability and handleability. It is the second set of yarns that imparts strength in the '446 patent.

Finally, the '446 patent teaches that lubricating yarns are "relatively weak." Ex. 8 col. 2, l. 25. In the tradeoff between braid strength and pliability, the '446 patent accepts the fact that the first set of yarn will somewhat weaken the braid because the increases in pliability from the first set of yarns will outweigh the loss of strength. Ex. 8, col. 2, ll. 26-28, 31-37; col. 8, ll. 19-49. The undisputed facts are that UHMWPE is strong, not weak. In light of these undisputed differences, the only possible conclusion is that the differences between the first set of yarns and UHMWPE is not insubstantial and accordingly, there can be no infringement by equivalents.

DePuy Mitek's attempts to create an equivalent argument where one does not exist through the report and testimony of its expert, David Brookstein. Dr. Brookstein uses a "function, way, result" test¹⁰ and concludes that UHMWPE is equivalent to the first set of yarns.¹¹ The function, way, result test is met if the function, way and result set forth in the patent for the limitation at issue (here, the first set of yarns) is the same as the function, way and result of the alleged equivalent material (UHMWPE). *Upjohn Co. v. Mova Pharmaceutical Corp.*, 225 F.3d 1306, 1309 (Fed. Cir. 2000).

The analysis that Dr. Brookstein sets forth, however, bears no relationship to the claims. For example, according to Dr. Brookstein, "[t]he function of the first set of yarns is to

¹⁰ The function, way result test can be used to decide the equivalents issue in appropriate cases. *Warner-Jenkinson*, 520 U.S. at 39-40.

¹¹ Dr. Brookstein could not decide at his deposition whether UHMWPE should be compared to the first set of yarns or just to PE. Ex. 29 at 276:11-15; 279:1-20. His report, however, makes the comparison to the first set of yarns.

contribute a property that is different from the second set.” Ex. 11 at ¶ 54. But Dr. Brookstein was forced to admit that *any* material would meet his functional identify as long as it contributed *anything* to the suture different from the second yarn. Ex. 28 at 284:4-10. Just to state the proposition is to demonstrate the absurd and unsupportable nature of the Brookstein test.

The simple fact is that the Brookstein recitation of function bears no relationship to the function of the first set of yarns set forth in the claims, as the law requires. The first set of yarns is comprised of the seven specific materials set forth in the claims. The patent leaves no doubt that a function of those materials is “to improve the overall pliability” of the braid. Ex. 8 at col. 4, ll. 12-13. The UHMWPE in FiberWire, of course, does not serve that function. It cannot because, as even Dr. Brookstein admits, it is too stiff. Ex. 11 at ¶ 56.¹² On this basis alone, the Brookstein analysis is fatally flawed.¹³

The prosecution history of the patent further reveals the flaw in Dr. Brookstein’s analysis. As the application was originally filed, it included broad claims which required only that there be two dissimilar yarns in direct intertwining contact. These original claims did not identify any specific materials. Ex. 22 at 18-20. But Ethicon abandoned these claims and instead only pursued the narrower claims which did identify the specific materials in each set of yarn. Ex. 25. While an argument could be made that Dr. Brookstein’s function and result have some relationship to these broad, abandoned claims, his analysis simply ignores the fact that these claims are not the claims at issue here. Dr. Brookstein admitted that he never considered the prosecution history in performing his function, way, result test. Ex. 28 at 288:15-23. If he

¹² Indeed, even Dr. Brookstein admits that the “flexibility,” *i.e.*, pliability function is served by the PET, not UHMWPE, in FiberWire. Ex. 11 at ¶ 64; Ex. 28 at 300:24-301:15.

¹³ Dr. Brookstein’s analysis of the “result” comparison suffers from the exact same problem. Ex. 11 at ¶¶ 61-63.

had, he would have realized that the function and result set forth in his report have no relationship to the function and result of the first set of yarns, as claimed in the '446 patent.

2. The Addition of Coating to FiberWire Avoids Infringement Because Coating Affects the Basic and Novel Characteristics of the '446 Patent

Patent claims typically include a transition phrase between the preamble of the claim and the rest of the claim. Most often, that transitional phrase is “comprising.” This means that the patent claim is “open”, that is, infringement is not avoided where the accused device includes materials in addition to those identified in the claim. *See, e.g., Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). Unlike the phrase “comprising,” the phrase “consisting essentially of” in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel properties of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). In this case, it is undisputed that FiberWire includes a coating, and that coating is not a listed item in the asserted claims. Thus, the sole issue is whether coating materially affects the basic and novel characteristics of the claims of the '446 patent. The undisputed facts show that it does and accordingly, there is no infringement.

The first step is to define the basic and novel characteristics of the claims of the '446 patent. This issue is discussed in detail in the *Markman* brief. *See Markman Br.* at 16-18. The second step is to determine whether coating materially affects those basic and novel characteristics.¹⁴ As we show below, the undisputed facts are that it does.

As shown in our *Markman* brief, the basic and novel characteristics of the claims of the '446 patent is having two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties. *See Markman Br.* at 16-18.

¹⁴ An effect on the basic and novel characteristics of the claimed invention is material if the affect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

The evidence overwhelmingly and undisputedly shows that coating materially affects the handleability aspects of the suture,¹⁵ particularly the knot tie down characteristics.¹⁶

That coating affects handleability characteristics of the braid, including knot tie-down, is so well known in the suture art that it hardly bears citation.

(1) Ethicon patent after Ethicon patent, including patents of Alistair Hunter, one of the inventors of the '446 patent, make that statement. *See* Ex. 34, col. 1, ll. 14-18 (“a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture”); Ex. 35, col. 1, ll. 11-15 (same); Ex. 36, col. 1, ll. 12-15 (“multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture”).

(2) A patent of Dr. Matthews Hermes, one of DePuy Mitek’s experts in this case, makes the same assertion. Ex. 37, col. 1, ll. 19-25 (“It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well”).

¹⁵ There is also significant evidence that coating affects the pliability of the suture as well as knot strength. Those issues, however, are not raised by this motion.

¹⁶ As Ethicon’s own Wound Closure Manual explains, knot tie down is the ease by which a knot slides down the suture. Ex. 29. A drawback of a braided suture is that it can be relative rough. As a result, when a surgeon slides a knot down the suture, the roughness may cause some “chatter” making it more difficult to tie a knot. Ex. 30 at col. 1, ll. 43-54. As DePuy Mitek and Ethicon witnesses observe, knot tie down is a well known suture handleability characteristic. Ex. 31 at 165:16-166:3; Ex. 32 at 94:19-95:6; Ex. 19 at 79:19-23. In fact, the '446 patent itself recognizes knot tie down as a handleability characteristic of a suture. Ex. 8 at col. 6, ll. 5-7.

Likewise, other known handleability characteristics include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. Ex. 33 at 20.

(3) Ethicon's Wound Manual makes the same point. Ex. 29 at 11 ("Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.").

(4) Articles in the field concur. *See* Ex. 28 at 525 ("synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics.").

(5) Ethicon and DePuy Mitek observed that coating affects handleability when developing its Orthocord product (which competes directly with FiberWire) and other suture products. *See, e.g.*, Ex. 39 (Orthocord is coated "for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide)."); Ex. 40 ("The purpose of coating the Panacryl suture is to provide the suture with handling properties.").

(6) Every DePuy Mitek and Ethicon witness who testified on the subject agreed. Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23.¹⁷

In light of this overwhelming evidence, it comes as no surprise that Arthrex's documents confirm that coating is added to improve handling characteristics. *See* Ex. 14 ("The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue). And if there were any doubt – and there is absolutely none, the '446 patent itself confirms that coating is added to improve handling characteristics of the suture, including knot tiedown *See* Ex. 8 at col. 1, ll. 29-31 ("multifilament sutures almost universally possess a

¹⁷ Incredibly, the only witness who did not readily agree was Dr. Brookstein, DePuy Mitek's so-called suture expert. When confronted with this overwhelming evidence, Dr. Brookstein's meek response was that had not reviewed the material (although he had had the opportunity to do so) and that he simply does not know if this is the known purpose of adding a coating. Ex. 28 at 167:14-169:6. The only conclusion that can be drawn from his testimony is either that Dr. Brookstein is not an expert on suture coating (a likely conclusion because he testified that he only worked on one suture project in his professional life and he did not remember if it involved issues of coating (Ex. 28 at 165:16-166:4)) or Dr. Brookstein simply cannot be believed.

surface coating to improve handling properties.”); col. 6, ll. 5-8 (“If desired, the surface of the heterogeneous multifilament braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid.”).

In short, the evidence is overwhelming and cannot be disputed. Coating affects the handleability of the suture – the same suture improvement that the ‘446 patent purports to achieve by its invention. Since the undisputed facts are that coating is added to FiberWire and coating materially affects the basic and novel characteristics of the claimed invention, there is no infringement.¹⁸

DePuy Mitek has no answer to this daunting evidence, so it incorrectly tries to change the question. According to its expert Dr. Brookstein, DePuy Mitek argues as follows: FiberWire was designed to have the two different yarns – UHMWPE and PET – contribute different properties to the braided suture. The contribution of different properties is present both before and after coating is added. Therefore, coating does not materially affect the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 24. DePuy Mitek comes to the same conclusion both under its and defendants’ view of the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 23.

¹⁸ The result is no different if the court were to accept DePuy Mitek’s view of the basic and novel characteristics of the claimed invention. According to DePuy Mitek, the basic and novel characteristics are “a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *See* Ex. 11 at ¶ 27; *see also* Ex. 44 at ¶ 28. As we understand DePuy Mitek’s position, it does not matter what property each yarn contributes to the suture, an added, unlisted material – here coating – affects the basic and novel characteristics as long as it affects the same suture property as one of the yarns.

PET is one of the yarns of the FiberWire braid. As DePuy Mitek itself contends, one of the purposes of the PET is to improve the knot tying ability of the suture braid. *See* Ex. 45 at ¶ 15. As shown above, this is one of the precise purposes of coating a suture. *See supra* at 13-16. Accordingly, even under DePuy Mitek’s view of the basic and novel characteristics of the claimed invention, coating has a material effect and its inclusion in FiberWire precludes a finding of infringement.

Stated another way, Dr. Brookstein asserts that coating does not affect the basic and novel aspects of the claimed invention because “the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided.” Ex. 44 at ¶ 27. When asked what this means, Dr. Brookstein replied that coating could only affect the basic and novel characteristics if “the coating in some *miraculous* way made those materials not yarns anymore” or “all of a sudden you had a set from A, a set from B and now it was some magical structure that wasn’t yarns, it wasn’t two sets, they were all the same, that would be a transformation.” Ex. 28 at 399-400, emphasis added. Just to state the proposition shows its absurdity. In DePuy Mitek’s and Dr. Brookstein’s world, only “magic” and “miracles” can cause an added material to affect the basic and novel characteristics of an invention. That plainly is wrong.

The most that could be said of DePuy Mitek’s position is that it believes that an added material that improves the basic and novel characteristics can never materially affect those characteristics, no matter how much the improvement. Indeed, Dr. Brookstein opined that coating could never affect the basic and novel characteristics even if it “improves one of the properties that one of the materials contributes to the braid.” Ex. 28 at 211:7-14. But the law is to the contrary. The Federal Circuit acknowledged that an added material can affect the basic and novel characteristics of an invention even if it only serves to improve those characteristics. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1246 (Fed Cir. 2001) (citing witness testimony that barrier layers are necessary for operation of accused product). *See also, Bayer A.G. v. Sony Electronics, Inc.*, 228 F. Supp.2d 332, 346-47 (D. Del. 2002) (stating that presence of cobalt materially affected the basic and novel properties of the claimed invention while citing witness testimony that the affect was to improve those properties); *Binney & Smith v. Rose Art Indus., Inc.*, 1995 U.S. Dist. LEXIS 2602 at *30 (N.D. Ill. 1995) (in denying injunctive relief due

to unlikelihood of success on infringement, court cited advantages of large volume of silicon dioxide in accused product as potential material affect); *American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.*, 172 F. Supp. 12, 19 (D. N.J. 1959) (stating improvements in water resistance were material affect of basic and novel characteristics).

DePuy Mitek's second argument is that coating cannot affect the basic and novel characteristics of the claimed invention because the '446 patent says that "if desired, the surface of the . . . braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid." Ex. 44 at ¶ 33. Depuy Mitek is wrong for several reasons. The short answer is that the law is to the contrary. In *AFG*, just like here, the patent stated that certain materials could be added. *AFG*, 239 F.3d at 1242. Notwithstanding that disclosure, the Federal Circuit acknowledged that use of such unlisted materials could materially affect the basic and novel characteristics of the invention. *AFG*, 239 F.3d at 1247. *See also, American Machine*, 172 F. Supp. at 19 (although additional substances were disclosed in specification, they were not in claims and could materially affect basic and novel characteristics).

Even if DePuy Mitek's argument had applicability in some circumstances, it would not apply here. As explained above, the claims, as originally submitted did not contain the "consisting essentially of" transitional phrase. Rather, the transitional phrase in the original claims was "comprising." For a "comprising" claim, it is no defense that the accused product has additional unlisted materials. *Free Motion*, 423 F.3d at 1353. Accordingly, it makes perfect sense, as the application was originally filed, that the patent would state that coating could be used, particularly because the patent recognizes that the coating improves certain handleability aspects of a suture. But once the transitional phrase "consisting essentially of" was added to the claim, which in turn narrowed the claim, DePuy Mitek's rationale falls apart.

Finally, an accurate reading of this passage of the patent shows that it supports *defendants'* position, *not* DePuy Mitek's. The passage asserts that coating improves suture handleability and knot tiedown, itself an *admission* that coating affects the basic and novel characteristics. The passage goes on to say that "if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, *the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.*" Ex. 8 at col. 6, ll. 13-17, emphasis added. That the patent teaches it is best to "eliminate[]" and "avoid[]" coating is graphic proof that its use in the accused product should lead to a finding of no infringement. *See, e.g., On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006) (claims may be construed to exclude a feature criticized in the specification).

For all the foregoing reasons, use of coating in FiberWire affects the basic and novel characteristics of the patent and, as a result, there is no infringement.

C. IF THE COURT CONSTRUES PE TO INCLUDE UHMWPE, THE '446 PATENT IS INVALID AS ANTICIPATED BY THE '575 PATENT

As explained in detail in Defendants' *Markman* brief, properly construed, the claim term "PE" means a general purpose polyethylene and does not include UHMWPE. If, however, the Court were to determine that the claim term PE does include UHMWPE, then the '446 patent is invalid as anticipated by the '575 patent.

A patent claim is invalid for anticipation where a single prior art reference discloses every limitation of the patent claim. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1321 (Fed. Cir. 2003). As long as the claimed invention is disclosed within the "boundaries of a single reference," the reference anticipates. *See, e.g., Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1577 (Fed. Cir. 1991). As we show below, the '575 patent is prior art to the '446 patent and, if PE is construed to include

UHMWPE, every limitation of the asserted claims of the ‘446 patent is disclosed within “the boundaries of” the ‘575 patent.

1. The ‘575 patent is prior art to the ‘446 patent

On its face, the ‘575 patent is prior art to the ‘446 patent under 35 U.S.C. § 102(e)(2) since it was filed prior to the filing date of the ‘446 patent.¹⁹ The only way DePuy Mitek can show that the ‘575 patent is not prior art is by providing evidence that it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent (*i.e.*, February 3, 1992). *See e.g., Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115 (Fed. Cir 1994) (burden of going forward with evidence of prior invention shifts to patentee once evidence of prior art is presented by defendant). In order to show it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent, DePuy Mitek must show that the claimed invention of the ‘446 patent was both conceived of and reduced to practice prior to the filing date of the ‘575 patent. *Id.*

According to its interrogatory answers and its expert submissions, DePuy Mitek argued that it can predate the ‘575 patent because Ethicon conceived of the invention by June 6, 1988 and reduced it to practice by February 1989. The undisputed facts, however, establish that Ethicon did not reduce the invention to practice prior to the date that it filed its patent application.

To establish reduction to practice, DePuy Mitek “must prove that [it] constructed an embodiment . . . *that met all the limitations of the claim*, and that [it] determined that the invention would work for its intended purpose.” *See e.g., Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). [Emphasis added.] *See also, Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) (“there cannot be a reduction to practice of the invention

¹⁹ The ‘575 patent was filed February 3, 1992, whereas the ‘446 patent was filed February 19, 1992. *Compare* Ex. 15 at cover page, Ex. 8 at cover page.

without a physical embodiment which includes all limitations of the claim”), *Hummer v. Administrator of Nat. Aeronautics and Space Admin.*, 500 F.2d 1383, 1387 (Ct. Cust. & Pat. App. 1974) (“to constitute an actual reduction to practice, the device demonstrated must include every limitation of the claim”) Thus, if even a single claim limitation is missing from what is built, there is no reduction to practice.

The undisputed evidence in this case is that Ethicon, through its inventor, Dr. Steckel, built and tested heterogeneous braids in February 1989. But one of the limitations of the asserted claims is that the product be a *sterilized* suture. The undisputed evidence is that the braids built and tested by Dr. Steckel were not “sterilized.” Dr. Steckel’s notebook makes no mention of sterilization in connection with any work on this project and Dr. Steckel confirmed that the heterogeneous braids he tested were not sterilized. Ex. 19 at 225:5-8. Likewise, Dr. Hermes confirmed that he had no evidence that Ethicon built a sterilized suture before the filing date of the ‘446 patent. Ex. 10 at 345:7-10.

Since, as a matter of law, reduction to practice requires that the embodiment constructed meet *all* the limitations of the claim, and since it is undisputed that the braids constructed by Dr. Steckel were not “sterilized,” a limitation of all the asserted claims of the ‘446 patent, DePuy Mitek can not predate the ‘575 patent by showing an earlier reduction to practice. Accordingly, the ‘575 patent is prior art to the ‘446 patent.

2. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent

As explained above (*supra* at 19), a patent claim is anticipated where a single prior art reference discloses every limitation of the claim. As we show below, every limitation of the asserted claims of the ‘446 patent is disclosed in the ‘575 patent.

- a. Independent claim 1 is anticipated by the ‘575 patent

For the convenience of the Court, we break down claim 1 of the '446 patent into its various limitations, and then we demonstrate that each limitation is disclosed in the '575 patent.

i. A surgical suture consisting essentially of

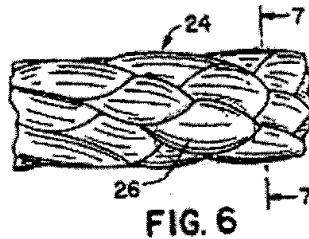
The '575 patent discloses a surgical suture. For example, the title of the '575 patent itself recites a method of using a "suture product." Since the '575 patent is directed to suture, it should come as no surprise that sutures are disclosed many times in connection with the '575 patent specification and drawings. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59.

Incredibly, DePuy Mitek, through its expert Dr. Hermes, tries to raise a factual dispute. Although Dr. Hermes conceded in his report that claim 1 of the '575 patent recites "a flexible elongated member," he stated that it was his "opinion" that this was limited to a sternum closure device and not a suture. Ex. 43 at ¶ 80. But Dr. Hermes simply ignores the disclosure of the '575 patent continually describing the elongated member as a suture. Moreover, when confronted with this evidence at his deposition, Dr. Hermes had no choice but to admit that the '575 patent does disclose flexible elongated members that are sutures. Ex. 10 at 212:25-213:5. Accordingly, Dr. Hermes's "opinion" is not supported by any factual basis and cannot create a dispute over a genuine issue of material fact. *See, e.g., Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1080-81 (Fed. Cir. 2005) (without a foundation or basis for an expert's opinion, that opinion alone does not rise to the level of "genuine issues of fact" to defeat a motion for summary judgment).

- ii. a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

The next limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that "first and second fibers" are "braided to form [an] elongated member." A person of ordinary skill in the art would plainly understand that this is a disclosure of two materials braided together in direct intertwining contact. See Mukherjee Rebuttal Report at 9. Even DePuy Mitek's expert meant "direct intertwining contact" when he used the term "braided" in his own patent. Ex. 45 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12.

Further, FIG. 6 of the '575 patent (reproduced below) discloses a spiroid braid with several yarns (items 26) that are braided in "direct intertwining contact," according to the construction agreed upon by the parties.



That is, FIG. 6 discloses that there is a "mechanical interlocking or weaving of the individual yarns [items 26] that make up the suture braid." Even Dr. Hermes agreed that FIG. 6 disclosed direct intertwining contact. Ex. 10 at 201:24-202:5.²⁰

DePuy Mitek has not attempted to contest that the vast majority of this limitation is disclosed in the '575 patent. The only aspect with which it attempts to take issue is the requirement that the one yarn from the first set is "in direct intertwining contact" with at least one yarn from the second set. According to DePuy Mitek, through its expert Dr. Hermes, the

²⁰ Furthermore, the disclosure of the '575 patent also acknowledges that the suture products must be sterilized. Ex. 15 at col. 1, line 36 (citing U.S. Patent No. 4,813,416, which discloses the need for sterilization with surgical products).

‘575 patent does not show any “direct intertwining contact” between the two different materials, one from each of the sets of yarns described in the ‘446 patent.²¹

In his report, Dr. Hermes opined that the claims of the ‘575 patent “do not recite that the first and second fibers are in direct intertwining contact, as opposed to a core-sheath arrangement.” Ex. 43 at ¶ 79. But, at his deposition, Dr. Hermes could not provide a single example of a braided construction that was not braided in “direct intertwining contact.” Ex. 10 at 212:25-213:5. Further, when confronted with the spiroid braid in FIG. 6 of the ‘575 patent (reproduced above), Dr. Hermes admitted that it disclosed “direct intertwining contact.” Ex. 10 at 201:24-202:5.

In short, there is absolutely no legitimate factual basis for Dr. Hermes’s opinion. The Federal Circuit has held that without a foundation or basis for an expert’s opinion, that opinion alone does not rise to the level of “genuine issues of fact” to defeat a motion for summary judgment. *Invitrogen*, 429 F.3d at 1080-81. The court also stated that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. *Id.* at 1080 (citing the Supreme Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986)). Likewise, here, DePuy Mitek has not raised a genuine issue of material fact.

- iii. a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

²¹ The only other place DePuy Mitek appears to contest the sufficiency of the disclosure of the ‘575 patent is in its response to Arthrex’s interrogatories. There, DePuy Mitek only contends that “Arthrex has failed to cite to a teaching of braided yarns as claimed in the ‘446 patent. Ex. 46. No reasoning or evidence is provided. A conclusion without support cannot raise a genuine issue of disputed fact. *See, e.g. TechSearch, L.L.C. v Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002). Thus, this interrogatory response cannot create a genuine issue of material fact.

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that the first fibers are "ultra high molecular-weight high tenacity material." The specification of the '575 patent specifically discloses that the ultra high molecular-weight high tenacity material is UHMWPE. Ex. 15 at col. 2, l. 31.

DePuy Mitek does not dispute this limitation. In fact, Dr. Hermes agreed that "ultra high molecular high tenacity material," as recited in claim 1 includes UHMWPE. Ex. 10 at 197:12-25

- iv. b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 11 of the '575 patent adds that the second fiber is nylon.

Although the '575 patent need disclose only one of these materials in this limitation to anticipate, it does disclose another material. For instance, claim 12 of the '575 patent adds that the second fiber is polyester.²²

DePuy Mitek does not dispute these disclosures. In fact, Dr. Hermes acknowledged these disclosures in the '575 patent at his deposition. Ex. 10 at 198:7-11, 14-18.

- v. c) optionally a core

Since this last limitation is optional, the '446 patent need not disclose it for the '575 patent to anticipate the '446 patent.

- b. The asserted dependent claims of the '446 patent are anticipated by the '575 patent

²² The specific polyester identified in the '575 patent is Dupont Dacron polyester (*i.e.*, a trade name for PET). Ex. 15 at col. 7.1.63. Moreover, DePuy Mitek's expert Dr. Brookstein asserted that polyester is synonymous with PET to those skilled in the suture art. Ex. 28 at 54:4-9.

The additional limitations added by the asserted dependent claims are also shown in the '575 patent.²³ Asserted claim 2 of the '446 patent adds that the suture is attached to a needle. The '575 patent also discloses the use of a needle attached to a suture. Ex. 15 at col. 5, ll. 41-42.

Asserted claim 8 of the '446 patent also adds that the second fiber-forming material is PET. As described, in n. 22, *supra*, the specific polyester identified in the '575 patent is Dupont Dacron polyester (i.e., a trade name for PET). Ex. 15 at col. 7, l. 63.²⁴

Asserted claim 9 also adds the PET requirement (the additional limitation from claim 8) and further adds that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent." As stated in the *Markman* brief, the parties have agreed that this claim term means that "the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture" ranges from about 20 to about 80 percent.

The '575 patent disclose a spiroid braided suture having one or more yarns of UHMWPE where the remainder of the yarns are non-absorbable yarns. Ex. 15 at col. 4, ll. 8-24; FIG. 6. Dr. Hermes agreed that FIG. 6 of the '575 patent discloses that more than one yarn (item 26) can be made of UHMWPE with and that one or more of the yarns (item 26) can be a non-absorbable yarn. Ex. 10 at 207:12-21. Since the '575 patent discloses that UHMWPE can make up any number of yarns of the suture, the '575 patent plainly includes a volume fraction of the first fiber-forming material between about 20-80%.

²³ As stated above, the asserted dependent claims all contain the limitations of claim 1 plus additional limitations. As we demonstrated above, the limitations from claim 1 (included in the dependent claims) are all disclosed by the '575 patent.

²⁴ Moreover, claim 12 of the '575 patent (Ex. 15 at col. 8, l. 62) discloses that the second fiber-forming material is polyester, a term synonymous with PET. *See supra* at n. 22.

Asserted claim 12 adds both the requirement that the second fiber forming material be PET (the additional limitation from claim 8) and that a needle be attached to the suture (the additional limitation of claim 2). For the same reasons discussed in connection with claim 2 and claim 8, claim 12 is also anticipated by the '575 patent.

For all the foregoing reasons, the asserted claims of the '446 patent are anticipated by the '575 patent.

IV. CONCLUSION

There are three independent reasons why summary judgment should be granted to defendants. There is no infringement because "PE" should not be construed to include UHMWPE. Therefore, FiberWire does not contain a yarn from the first set. The addition of coating to FiberWire leads to a finding of non-infringement because the undisputed evidence is that coating affects the basic and novel characteristics of the '446 patent. Finally, if the Court were to construe the term "PE" to include UHMWPE, the asserted claims of the '446 patent are invalid because the '575 patent discloses each limitation of those claims.

For all the foregoing reasons, summary judgment should be granted and DePuy Mitek's claims should be dismissed in their entirety.

Dated: August 11, 2006

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Substitute Memorandum in Support of Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Motion for Summary Judgment, and Substitute Concise Statement of Material Facts in Support Thereof were served, via the Court's email notification system on the following counsel for Plaintiff on the 29th day of August 2006:

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SUBSTITUTE EXHIBIT 10

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

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DePUY-MITEK, INC.,

A Massachusetts Corporation,
Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,
Defendants.
-----x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

1 invention during the time you were working at US
2 Surgical?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: I don't recall.

5 BY MR. SABER:

6 Q. Would this definition of braid or
7 braided that you used in this patent result in yarns
8 that are in direct intertwining contact as you
9 understand that term from the '446 patent?

10 A. It's my opinion that the -- that the
11 sheath yarns would be in direct intertwining
12 contact.

13 Q. Now, in -- in your patent, this
14 definition of braid or braided didn't require that
15 there be a core, correct?

16 A. It did not require that there be a
17 core, that is correct.

18 Q. And the -- on column three, line ten,
19 it says the braided suture of this invention can
20 optionally possess in addition to the braided
21 structure itself a core component around which the
22 braid is constructed?

23 A. Yes.

24 Q. Is that correct?

25 A. That's correct, that's what it reads.

1 Q. Do you agree that Figure 6 is an
2 elongated member?

3 A. Yes, I do.

4 Q. And same thing about Figure 8?

5 A. Yes, I -- yes, sir.

6 Q. Okay. You would agree that this
7 patent discloses elongated members that are sutures,
8 correct?

9 A. I would agree that this patent
10 discloses elongated members, some of which are
11 described as sutures, yes.

12 Q. Let's go back to claim one, column
13 eight.

14 A. Yes, sir.

15 Q. Would you agree with me that the
16 first fiber includes ultra high molecular weight
17 polyethylene?

18 A. Claim one?

19 Q. Yes, sir.

20 A. Yes. It says ultra high molecular
21 weight, high tenacity is the material.

22 Q. And under this patent, that would
23 include ultra high molecular weight polyethylene?

24 A. If that's a question, I believe it
25 would, yes.

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Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 Q. Okay. And now there's also -- the
2 ultra high molecular weight polyethylene in claim
3 one is braided with a second fiber, correct?

4 A. That is correct.

5 Q. And could you look to claim 11?

6 A. Yes.

7 Q. And does claim 11 -- would you agree
8 with me that claim 11 says that the second fiber
9 that's braided with the ultra high molecular weight
10 polyethylene is nylon?

11 A. Yes.

12 Q. Could you look at claim 12?

13 A. Yes.

14 Q. Would you agree with me that that
15 says that the second fiber braided with the ultra
16 high molecular weight polyethylene is polyester?

17 MR. BONELLA: Object to the form.

18 THE WITNESS: Yes.

19 BY MR. SABER:

20 Q. Is there -- in claim one, is there
21 any mention of a core?

22 A. No.

23 Q. In claim 11, is there any mention of
24 a core?

25 A. No.

1 together and there's no core, that that's one of the
2 things that falls within claim 11?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. SABER:

6 Q. Okay. And same thing with respect to
7 claim 12?

8 A. Yes.

9 MR. BONELLA: Object to the form.

10 THE WITNESS: I'm sorry. Yes.

11 BY MR. SABER:

12 Q. The -- could you look back at Figure
13 6?

14 A. Yes.

15 Q. Are the -- the various yarns 26 that
16 are shown in Figure 6, are they in direct
17 intertwining contact with each other?

18 A. It's my opinion that -- yarns 26 as
19 described in --

20 MR. BONELLA: Object to the form of
21 the question.

22 MR. SABER: Let me rephrase it.

23 BY MR. SABER:

24 Q. Do you agree that the yarns 26 --
25 that are denoted as 26 in Figure 6?

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1 A. Yes.

2 Q. Right? That those yarns are in
3 direct intertwining contact as that term is used in
4 the '446 patent?

5 A. I believe they are, yes.

6 Q. Let me ask you about Figure 8. Do
7 you see the yarns denoted by the numbers 30?

8 A. Yes.

9 Q. Do you agree that the yarns denoted
10 by number 30, Figure 8, are in direct intertwining
11 contact with each other as that term is used in the
12 '446 patent?

13 A. I believe that they're in direct
14 intertwining contact with each other as sheath
15 yarns. The core yarn is not.

16 Q. Well, the 30s are all in the sheath,
17 correct?

18 A. Yes, sir.

19 Q. Right. And the 30s are not in the
20 core, correct?

21 A. Yes.

22 Q. I was asking about the 30s.

23 A. Yes, sir.

24 Q. Just so the record is clear, do you
25 agree that the yarns 30 from Figure 8 are in direct

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Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 A. I do not have that understanding. I
2 understood your question and that is my answer.

3 Q. Okay. Assume with me that each one
4 of the yarns -- do you see in Figure 6 there are a
5 dozen or so yarns that are depicted?

6 A. Yes, sir.

7 Q. Assume with me that each one of those
8 is a 26.

9 A. We can do that.

10 Q. Okay.

11 A. Yes, sir.

12 Q. Would you agree with me that at least
13 one of those 26s is ultra high molecular weight
14 polyethylene?

15 A. Yes.

16 Q. And do you understand that more than
17 one can be ultra high molecular weight polyethylene?

18 A. Yes.

19 Q. And do you have an understanding that
20 one or more of the 26s can be a nonabsorbable yarn?

21 A. Yes.

22 Q. Let me turn to the Burgess
23 application, which is Exhibit 7 to your report, your
24 first report.

25 A. Yes, sir.

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Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 question, if I may.

2 Am I correct that you don't provide
3 an example of a braided construction without direct
4 intertwining contact where there is no core in your
5 report?

6 MR. BONELLA: Object to form.

7 BY MR. SABER:

8 Q. Let me rephrase that again.

9 A. Yeah, try it again.

10 Q. In your report am I correct that you
11 provide no example of a braided construction where
12 there is no direct intertwining contact of a -- of a
13 construction that does not have a core?

14 A. See if this answers your question. I
15 do not believe in my report that I provide in a
16 noncore construction a braid without intertwining
17 contact.

18 Q. Without direct intertwining contact?

19 A. Without direct intertwining contact.

20 Is that --

21 Q. That answers my question.

22 A. Is that an answer to your question?

23 Q. Yes, sir, it is.

24 A. Okay.

25 Q. And as you sit here today, can you

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Dr. Matthew Hermes, Vol. I

June 27, 2006

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1 give me an example of a braided construction which
2 does not have direct intertwining contact where
3 there is no core?

4 A. I'd have to think about it. I don't
5 know the answer to that.

6 Q. Okay.

7 MR. SABER: Why don't we take a break
8 at this point?

9 THE VIDEOGRAPHER: Going off the
10 record.

11 The time on the video monitor is
12 4:04 PM.

13 (Recess.)

14 THE VIDEOGRAPHER: Going back on the
15 record. The time on the video monitor is 4:24 PM.

16 Please continue.

17 BY MR. SABER:

18 Q. Dr. Hermes, I'd like to ask you a
19 little bit about the Cohan article, if I'm
20 pronouncing that correctly, which I believe is
21 Exhibit 8 to your report.

22 A. Yes, sir.

23 Q. The -- would you -- would you agree
24 with me that the Cohan article discloses the use of
25 ultra high molecular weight PE in a suture

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

		Page 345
1	Q. -- the date -- the date of -- the	01:15:49p
2	filing date of the '446 patent?	01:15:50p
3	MR. BONELLA: That was a	01:15:52p
4	different question.	01:15:53p
5	MR. SABER: Let me rephrase it.	01:15:53p
6	BY MR. SABER:	01:15:55p
7	Q. Do you have any evidence that Ethicon	01:15:55p
8	sterilized a suture within the claims of the '446	01:15:58p
9	patent prior to the filing date of that patent?	01:16:02p
10	A. I have no such evidence.	01:16:06p
11	Q. Now, the February 2, 1989, sutures	01:16:12p
12	that you discuss in your report were not	01:16:16p
13	sterilized, isn't that correct?	01:16:18p
14	A. I don't know that. They're not	01:16:19p
15	described as sterilized, but I certainly don't	01:16:20p
16	know that for certain.	01:16:23p
17	Q. Did you review Dr. Steckel's testimony	01:16:24p
18	where he talked about whether those sutures were	01:16:31p
19	sterilized?	01:16:36p
20	A. If he talked about it, I don't	01:16:37p
21	remember what he said.	01:16:38p
22	Q. Let's see if we can --	01:16:39p
23	MR. SABER: Could you mark this	01:16:42p
24	as the next exhibit.	01:16:43p
25	(Whereupon a document was	01:16:47p

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

		Page 346
1	marked, for identification purposes, as	01:16:47p
2	Defendant's Exhibit-194.)	01:16:48p
3	MR. BONELLA: Thank you.	01:17:18p
4	BY MR. SABER:	01:17:18p
5	Q. Let me show you Dr. -- or at least the	01:17:18p
6	second volume of Dr. Steckel's deposition, and I	01:17:23p
7	just want to draw your attention to a couple of	01:17:27p
8	pages.	01:17:29p
9	This is -- we've shown you	01:17:31p
10	what's been marked as Defendant's Exhibit-194	01:17:32p
11	which is the second volume of Dr. Steckel's	01:17:35p
12	deposition.	01:17:40p
13	A. And that's what I have, Mr. Saber,	01:17:40p
14	thank you.	01:17:44p
15	Q. Yes, sir. And if you could look at	01:17:44p
16	Page 221 of that?	01:17:46p
17	A. Okay.	01:17:48p
18	Q. You see that there's a discussion of	01:17:49p
19	the February 2, 1989, entry from his lab	01:17:53p
20	notebook?	01:17:56p
21	A. (Witness reviewing document.)	01:18:20p
22	Where's the beef?	01:19:22p
23	Q. Page 221 of his deposition --	01:19:22p
24	A. Mm-hmm, okay.	01:19:24p
25	Q. -- is where that's discussed. Do you	01:19:25p

SUBSTITUTE EXHIBIT 19

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 DEPOSITION of DR. MARK G. STECKEL,

13 called as a witness by and on behalf of the
14 Defendant, pursuant to the applicable provisions of
15 the Federal Rules of Civil Procedure, before P.
16 Jodi Ohnemus, Notary Public, Certified Shorthand
17 Reporter, Certified Realtime Reporter, and
18 Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Courtyard
20 Marriott, 423 Speen Street, Natick, Massachusetts,
21 on Thursday, 26 January, 2006, commencing at 10:44
22 a.m.
23
24
25

1 Q. Yes, one of the things. I didn't mean
2 that to be the only thing.

3 A. Okay. Well --

4 Q. That's fine.

5 A. Yeah.

6 MR. BONELLA: Object to form.

7 Q. I asked you if you needed a clarification
8 to do that.

9 A. Yeah.

10 Q. So, that's why.

11 A. Okay. So, yes, that was one of the things
12 that it could have contributed to.

13 Q. Anything else on handling properties?

14 MR. BONELLA: Object to form.

15 A. It's been a while since I've been in the
16 suture business, but I can't think of anything else
17 that it would have -- that it would relate to,
18 other than what we just described for handling.

19 Q. Is it -- how about how the knot is tied --
20 knot tie-down, or is knot tie-down part of the same
21 thing as chatter?

22 A. Knot tie-down is part of the same handling
23 properties. And the -- how tight the knot gets is
24 also related, and that's -- going back to the
25 question, if I could, on knot strength, the

1 Ethicon had multiple development programs going,
2 some of which were to make a product that were --
3 had better properties than silk, and silk has
4 really good handling properties. Some of them had
5 to do with higher strength sutures. Some of them
6 had to do with different biologic profiles in terms
7 of strength retention over time. And the initial
8 discussions were how can we address those types of
9 problems with a combination of fiber types.

10 So, the initial conversations -- and one
11 of the avenues that came out of that was this maybe
12 opportunity to have a suture that has strength
13 better than silk, but pliability like silk. So,
14 that was one of them.

15 Q. Okay.

16 A. And that was one that Al and Art had
17 considered in the past. Again, I'm not clear how
18 far they took that in the past, but they at least
19 considered that. And that was one that we elected
20 to pursue earlier than later, because we had the
21 materials, essentially. We thought it was good
22 opportunity.

23 Q. So, if I understand your testimony -- at
24 least at the very beginning stage you wanted
25 something that was stronger than silk but handled

1 as well as silk, is that --

2 A. That was certainly one of the embodiments
3 we were going after.

4 Q. As the -- as the project -- as the
5 project progressed and as you applied for a patent,
6 is it correct that you were trying to get something
7 that handled better than a homogenous braid but
8 didn't lose strength -- appreciably lose strength
9 from the conventional homogenous braid?

10 A. The overall project, yeah, I think that
11 was -- that would be a fair assessment of the
12 objective of the overall project.

13 Q. All right. And the conventional
14 homogenous braid that you were talking about that
15 you wanted to not lose appreciative strength then
16 was Ethibond, is that correct?

17 A. Right. Ethibond -- well, Ethibond, you
18 know, had good strength, but maybe not as good
19 handling properties as silk,.

20 Q. Right.

21 A. Silk had lower strength, good handle
22 properties, and again, one of the concepts was we
23 -- maybe we could get the best of both.

24 Q. All right. But as you applied for the 446
25 patent, was it the object there to have something

1 interest in how do you improve the knot strength of
2 them, and can you -- that was -- that was something
3 we discussed.

4 Q. I'm not sure I understand your answer.

5 A. Go ahead.

6 Q. And I'm trying to --

7 A. Sure.

8 Q. When you had this idea that you could
9 blend Dyneema together with PET, were you -- did
10 you believe it would make an acceptable suture or
11 an unacceptable suture?

12 A. No. We believed -- we believed that that
13 could offer a suture with straight tensile that was
14 better than Ethibond, and you know, could
15 potentially solve the knot issues, and again, that
16 was a generic view for all of the high-tenacity
17 fibers.

18 Q. You thought it was a good idea --

19 A. Yes. Yes.

20 Q. -- rather than a bad idea?

21 A. No, we viewed -- we viewed that as a
22 potential good idea.

23 Q. And you didn't think, Oh, that's a bad
24 idea.

25 MR. BONELLA: Objection. Asked and

Continued Deposition of:
Dr. Mark Steckel, Vol. II

February 3, 2006

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1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4 DAY II

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 CONTINUED DEPOSITION of DR. MARK

13 G. STECKEL, called as a witness by and on behalf of
14 the Defendant, pursuant to the applicable
15 provisions of the Federal Rules of Civil Procedure,
16 before P. Jodi Ohnemus, Notary Public, Certified
17 Shorthand Reporter, Certified Realtime Reporter,
18 and Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Hilton Hotel,
20 25 Allied Drive, Dedham, Massachusetts, on Friday,
21 3 February, 2006, commencing at 9:06 a.m.

1 Q. Were the braids -- was a tipping put on
2 the braids?

3 A. There would not be tipping, since we never
4 intended to attach needles to this evaluation.

5 Q. Were the braids sterilized?

6 A. Typically at this level -- the answer is,
7 I believe, no. At this point in an evaluation, we
8 would typically evaluate presterile properties.

9 Q. Okay. Could you turn to Page 2638. So,
10 the fourth page of the --

11 A. Yes.

12 Q. -- fourth page of this -- the entry.
13 Under "Discussion," the first sentence says, "From
14 a braid processing viewpoint, the commingled yarn
15 was the least problematic braid, followed by the
16 yarn blend. The carrier blend presented the most
17 difficulties in core popping and braid looseness."

18 What did you mean by "The carrier blends
19 presented the most difficulties in core popping and
20 braid looseness"?

21 A. Core popping is a common braid defect.
22 You know, any braid text would -- would cover it.
23 The ability to adjust the tension on the yarn that
24 affects core popping was more difficult with the
25 carrier blend and the yarn blend than the

1 Q. Could you read her note for the record,
2 please.

3 A. Yes. "Being reviewed as potential new
4 product for Ethicon. May offer significant
5 advantages if technical problems of mixing of
6 materials with dissimilar stress/strain properties
7 can be overcome."

8 Q. Okay. Do you have an understanding of
9 what was meant by "-- if technical problems of
10 mixing of materials with dissimilar stress/strain
11 properties can be overcome"?

12 A. I believe she's referring to the tension
13 issues on processing the heterogeneous yarns.

14 Q. That we've discussed last week and earlier
15 today?

16 A. That would be my understanding.

17 Q. All right. And is it your understanding
18 that those --

19 A. Although this is Barbara's words, not
20 mine.

21 Q. That's what I'm trying to under -- to get
22 your understanding.

23 A. Yeah.

24 Q. And is it your understanding that those
25 technical problems with tension had not yet been

1 overcome as of February 8th, 1990?

2 MR. BONELLA: Object to the form.

3 A. I don't know if -- if Barbara at the
4 director level or manager level would have had
5 firsthand knowledge of that, so --

6 THE WITNESS: I'm sorry. Could you repeat
7 the question.

8 (Question read back.)

9 A. Once again, I think we're in the realm of
10 manufacturing requirements versus proof of concept
11 requirements in terms of have the technical
12 problems been overcome?

13 Q. Well, was it your understanding that --
14 well, do you understand -- do you know the basis of
15 Ms. Schwartz's comment, what that was based upon --
16 what her comment was based upon?

17 A. No, I'm inferring it from -- from the
18 comments and from what we've read.

19 Q. Okay. So, do you have an understanding
20 one way or another exactly what she was talking --
21 well, strike that.

22 MR. SABER: Why don't we take our break.

23 (Recess was taken.)

24 Q. Doctor Steckel, there came a time, of
25 course, when Ethicon applied for the 446 patent, of

1 A. To the amount of surface area in the
2 multifilament braid and the potential for -- let's
3 just leave it at that: The amount of surface area
4 between a multifilament versus a monofilament.

5 Q. Does it have to do with the roughness of
6 the braid versus smoothness of the braid?

7 A. Less to do with that, more to do with the
8 fact that the multifilament braid has interstices
9 (sp) that, you know, could potentially harbor
10 bacteria, etcetera.

11 Q. Going back to this paragraph that begins
12 at Line 26, it then goes on to speak about, "For
13 example, multifilament sutures almost universally
14 possess a surface coat to improve handling
15 properties." Is improving handling properties one
16 of the specific properties of multifilament braids
17 that is -- that coating -- that this paragraph is
18 saying coating is designed to improve?

19 MR. BONELLA: Object to form.

20 A. I'm sorry.

21 Q. Let me rephrase that. That was --

22 A. Yeah. I'm sorry.

23 Q. It says, "For example, multifilament
24 sutures almost universally possess a surface
25 coating to improve handling properties." Do you

1 **see that?**

2 A. Yes.

3 **Q. What's your understanding of what handling**
4 **properties are being referred to in that sentence?**

5 A. My understanding, because the surface
6 coating would be for knot handling, knot tie-down
7 handling properties.

8 **Q. Knot tie-down?**

9 A. Knot tie-down.

10 **Q. Anything else?**

11 A. Not to my understanding.

12 **Q. How about how well the knot slides, is**
13 **that one of the things that --**

14 A. Oh, yeah. That's part of knot tie-down.

15 **Q. Why don't you explain to me what is part**
16 **of knot tie-down.**

17 A. Okay. Yeah. I mean, knot tie-down refers
18 to the properties of a suture during the tying
19 process, which would include the force, smoothness,
20 roughness when one arm of the suture is being
21 pulled against the second arm of the suture.

22 **Q. How about is -- is coating designed to**
23 **help the -- the suture go through tissue more**
24 **easily?**

25 MR. BONELLA: Objection. Calls for expert

SUBSTITUTE EXHIBIT 28

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

	Page 54
1 of the question.	08:59:18a
2 THE WITNESS: I have no --	08:59:19a
3 BY MR. SABER:	08:59:20a
4 Q. Is it PET?	08:59:20a
5 A. PET and polyester are used	08:59:21a
6 interchangeably, yes. The polyethylene	08:59:23a
7 terephthlate is the official chemical name for	08:59:28a
8 polyester. Polyester is essentially a shorthand	08:59:32a
9 way of referring to polyethylene terephthlate.	08:59:36a
10 Q. Okay.	08:59:40a
11 A. Whenever you see those terms, they're	08:59:41a
12 the same thing.	08:59:42a
13 Q. Polyester, or...?	08:59:43a
14 A. Polyester and polyethylene	08:59:43a
15 terephthlate, T-E-R-E-P-T-H-L-A-T-E, and polyester	08:59:51a
16 are used interchangeably, in the literature, in	09:00:00a
17 the science, in teaching, by everybody.	09:00:03a
18 Q. Okay. And poly -- I have a little	09:00:09a
19 trouble with this --	09:00:12a
20 A. Okay.	09:00:15a
21 Q. -- polyethylene terephthlate --	09:00:15a
22 A. Terephthlate.	09:00:16a
23 Q. -- is referred to as PET?	09:00:16a
24 A. That is correct.	09:00:17a
25 Q. The -- could you -- I just want to tie	09:00:19a

	Page 165
1 about sutures, but actually designing and	11:16:23a
2 developing and the quality associated with that	11:16:25a
3 was for U.S. Surgical; I don't recall if we	11:16:32a
4 coated or not.	11:16:34a
5 Q. You just don't remember from that	11:16:35a
6 project?	11:16:38a
7 A. Right.	11:16:38a
8 Q. Do you recall whether you've had any	11:16:38a
9 experience with respect to coating of sutures in	11:16:40a
10 your background prior to your work on this case?	11:16:44a
11 A. I don't recall, because, you know, we	11:16:49a
12 looked at the vascular prosthesis patent that had	11:16:51a
13 sutures on it, I don't recall if they were coated	11:16:53a
14 or not. I don't know.	11:16:56a
15 Q. Have you -- do you recall whether you	11:16:58a
16 have had any experience with respect to what	11:17:01a
17 coating -- how coating impacts on suture	11:17:08a
18 properties?	11:17:11a
19 A. Well, I've looked at the Gitis report	11:17:15a
20 and tried to --	11:17:19a
21 Q. I'm sorry, prior to your work in this	11:17:20a
22 case.	11:17:21a
23 A. Not prior to the work in this case.	11:17:22a
24 Q. Okay. The -- would it be correct to	11:17:23a
25 say that what you've learned about coating and	11:17:31a

	Page 166
1 its impact on suture properties is in conjunction	11:17:33a
2 with your work on this case?	11:17:35a
3 A. That would be proper to say that, yes.	11:17:38a
4 Q. The -- do you have an opinion as to	11:17:44a
5 whether it is generally well-known in the suture	11:17:45a
6 art that coating multifilament suture improves	11:17:48a
7 the tactile smoothless -- smoothness, pliability,	11:17:53a
8 and knot tie-down performance of that suture?	11:17:58a
9 A. That's a long question. Do that --	11:18:02a
10 let's do that slower and --	11:18:05a
11 Q. Sure, I'll even try to take it into	11:18:06a
12 parts.	11:18:09a
13 A. Yeah.	11:18:09a
14 Q. Do you have an opinion -- well, let me	11:18:09a
15 ask you this. Is it correct that it is generally	11:18:12a
16 known in the suture art that coating a	11:18:14a
17 multifilament suture improves the tactile	11:18:16a
18 smoothness of the suture?	11:18:18a
19 MR. BONELLA: Objection; incomplete	11:18:22a
20 hypothetical.	11:18:23a
21 THE WITNESS: I haven't seen	11:18:24a
22 anything that says that.	11:18:25a
23 BY MR. SABER:	11:18:26a
24 Q. You don't have an opinion one way or	11:18:26a
25 the other?	11:18:28a

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11:18:28a

11:18:29a

11:18:31a

11:18:35a

11:18:39a

11:18:40a

11:18:41a

11:18:42a

11:18:43a

11:18:45a

11:18:45a

11:18:47a

11:18:47a

11:18:49a

11:18:52a

11:18:52a

11:18:52a

11:18:55a

11:18:56a

11:18:58a

11:19:00a

11:19:06a

11:19:09a

11:19:16a

11:19:20a

	Page 168
1 multifilament suture improves the knot tie-down	11:19:22a
2 performance of that suture?	11:19:25a
3 MR. BONELLA: Objection; incomplete	11:19:27a
4 hypothetical.	11:19:29a
5 THE WITNESS: I've seen no	11:19:29a
6 evidence where that's discussed.	11:19:31a
7 BY MR. SABER:	11:19:33a
8 Q. So you don't have an opinion one way	11:19:33a
9 or the other?	11:19:37a
10 MR. BONELLA: Objection;	11:19:37a
11 incomplete --	11:19:38a
12 BY MR. SABER:	11:19:39a
13 Q. Is that correct?	11:19:39a
14 MR. BONELLA: Incomplete	11:19:40a
15 hypothetical on that previous question.	11:19:41a
16 THE WITNESS: My opinion is	11:19:43a
17 that coating only has an immaterial effect that	11:19:43a
18 might -- might -- affect handleability, and	11:19:47a
19 that's all.	11:19:51a
20 BY MR. SABER:	11:19:51a
21 Q. What is that opinion based on?	11:19:51a
22 A. It's based mostly on some of the work	11:19:53a
23 I've read from Gitis. It's an opinion of looking	11:19:55a
24 at the micrographs that I took and seeing the	11:19:59a
25 level of coating that was on those sutures. It's	11:20:02a

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1	a -- it's based on some theoretical calculations	11:20:06a
2	I made associated with bending rigidity. It's	11:20:12a
3	understanding how tensile properties of fibers	11:20:17a
4	relate to the tensile properties of the braided	11:20:21a
5	structure. In no case can you show that coating	11:20:24a
6	does anything of any material. It's almost an	11:20:27a
7	afterthought to put it on.	11:20:31a
8	I think the patent even says, you	11:20:45a
9	know, in some cases it's expensive, don't even	11:20:46a
10	bother with it, it's not that a big deal. It's	11:20:51a
11	expensive and don't even put it on it.	11:20:54a
12	Q. Just give me a moment.	11:20:57a
13	A. I just want to read from the patent.	11:21:09a
14	MR. BONELLA: Why don't you wait	11:21:12a
15	until there's a question.	11:21:13a
16	THE WITNESS: Okay. Okay. Okay.	11:21:14a
17	MR. BONELLA: There's no question.	11:21:15a
18	(Whereupon a document was	11:21:32a
19	marked, for identification purposes, as	11:21:32a
20	Defendant's Exhibit-202.)	11:21:33a
21	THE VIDEOGRAPHER: Going off the	11:21:54a
22	video record.	11:21:55a
23	(A discussion was held off the	11:22:15a
24	record from 11:21 AM to 11:22 AM, with the video	11:22:15a
25	record then resuming.)	11:22:20a

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1 from the second set, and the dissimilar yarns	12:02:23p
2 have at least some different properties that	12:02:28p
3 contribute to the overall properties of the	12:02:31p
4 braid. That is what I've been asked to assume.	12:02:31p
5 That is what my opinions are based on, those	12:02:33p
6 basic and novel characteristics.	12:02:36p
7 Q. In your opinion, sir, if the coating	12:02:38p
8 improves one of the properties that one of the	12:02:40p
9 materials contributes to the braid, can it have a	12:02:42p
10 -- can it materially affect the basic and novel	12:02:45p
11 characteristics of the invention?	12:02:48p
12 A. Not under this definition, no.	12:02:50p
13 Q. Your answer is no?	12:02:51p
14 A. The answer is no.	12:02:52p
15 Q. Okay.	12:02:55p
16 MR. SABER: Mike, this is	12:02:55p
17 probably a pretty good time.	12:02:56p
18 MR. BONELLA: Okay.	12:03:00p
19 BY MR. SABER:	12:03:00p
20 Q. What's the basis for that opinion?	12:03:00p
21 A. The basis for what opinion?	12:03:01p
22 Q. What you just said, that even if it	12:03:02p
23 improves the property that one of the yarns adds,	12:03:05p
24 it cannot affect the basic and novel	12:03:10p
25 characteristics.	12:03:12p

		Page 276
1	equivalents?	02:29:00p
2	A. Okay. Let me -- let me go through my	02:29:05p
3	report.	02:29:07p
4	First we look at each -- you make	02:29:07p
5	a table and we look at each claim or claim	02:29:10p
6	element and we see what that claim element or	02:29:13p
7	claim is claiming.	02:29:17p
8	Then we look under the function	02:29:18p
9	of the claim limitation. Okay? We see what it	02:29:21p
10	-- what is it -- what is the function of this, we	02:29:25p
11	make a determination what the function is, and	02:29:26p
12	then we compare it to what the function is of the	02:29:28p
13	material that's in question and we match the	02:29:31p
14	functions. Okay?	02:29:33p
15	Then we see -- once we've	02:29:34p
16	determined what the function is, we see the way	02:29:37p
17	that it met that function. And after that, we	02:29:40p
18	see what the final results are.	02:29:43p
19	So we're always -- we take the	02:29:43p
20	claim. Okay? We decide what the function,	02:29:45p
21	way or result is that we're trying to achieve,	02:29:49p
22	and then we look at the material in question	02:29:51p
23	and see if it meets the function, way and	02:29:53p
24	result for it to be an insubstantial	02:29:56p
25	difference.	02:29:58p

	Page 279
1 yarn from the second set.	02:33:10p
2 A. Right.	02:33:13p
3 Q. Correct?	02:33:13p
4 A. Right.	02:33:14p
5 Q. Now, was that your opinion or was that	02:33:14p
6 the function -- was that function given to you by	02:33:16p
7 the attorneys?	02:33:19p
8 A. No, it was the function that I got	02:33:19p
9 from the '446 patent. It says, My opinion	02:33:21p
10 regarding the function of the first fiber	02:33:25p
11 material is supported by the '446.	02:33:27p
12 Q. No --	02:33:29p
13 A. Let me --	02:33:30p
14 Q. I just want you to answer my	02:33:31p
15 question. I mean, was this -- I'm just trying to	02:33:33p
16 find out does this -- are you the one who came up	02:33:36p
17 with the function, or was that something that was	02:33:39p
18 an assumption that was given to you by the	02:33:40p
19 attorneys?	02:33:43p
20 MR. BONELLA: Objection. Asked	02:33:43p
21 and answered.	02:33:44p
22 BY MR. SABER:	02:33:44p
23 Q. That's my question.	02:33:44p
24 A. Mr. Falke explained to me how the	02:33:47p
25 function/way result works from a legal	02:33:50p

	Page 284
1 test that you set forth for function?	02:38:36p
2 A. Can you repeat that, or can you read	02:38:42p
3 it back?	02:38:44p
4 Q. Let me rephrase it.	02:38:46p
5 Am I correct that any yarn would	02:38:48p
6 meet the function test, as you set forth, as long	02:38:54p
7 as it contributed a property to the suture	02:38:58p
8 different from the property contributed by the	02:39:01p
9 yarn of the second set?	02:39:03p
10 A. That is what I wrote, yes.	02:39:05p
11 Q. In coming up with the function, did	02:39:13p
12 you consider the function set forth -- the	02:39:18p
13 function set forth in the patent for the specific	02:39:23p
14 yarns identified in the first set of yarns?	02:39:27p
15 A. Yes, I say that. If we go to the --	02:39:32p
16 if we go to the patent and I'll show you where	02:39:35p
17 that is. It's right here (indicating), under Tab	02:39:37p
18 D, Column 2, Lines 50 to 52, and Column 3, Lines	02:39:41p
19 43 to 48. I think that's in the -- I cited the	02:39:51p
20 patent there.	02:39:56p
21 Do you want to go to the patent	02:39:57p
22 and we can talk about it?	02:39:58p
23 Q. Sure. Let's start with -- I do want	02:39:59p
24 to ask you a couple of questions about that.	02:40:03p
25 A. Okay.	02:40:06p

		Page 285
1	Q. The first thing you say is Column 2,	02:40:06p
2	Lines 50 to 52, in the patent?	02:40:08p
3	A. Yes.	02:40:11p
4	Q. And this is Exhibit D?	02:40:11p
5	A. Yes, sir.	02:40:14p
6	Q. And that's the sentence that begins,	02:40:14p
7	Surprisingly --	02:40:16p
8	A. Yes.	02:40:17p
9	Q. -- the heterogeneous braids may	02:40:17p
10	exhibit -- well, tell me specifically what in	02:40:19p
11	that, because I know the numbers get a little bit	02:40:22p
12	off, as we know.	02:40:24p
13	A. I understand.	02:40:25p
14	Q. Tell me specifically what you're	02:40:26p
15	referring to at Column 2, Lines 50 to 52.	02:40:27p
16	A. Well, I also have it in my -- in my	02:40:31p
17	report, the -- I quoted, The patent explains that	02:40:35p
18	the first fiber-forming material is dissimilar to	02:40:38p
19	the second set -- second fiber, and the braid of	02:40:41p
20	the similar yarns provides, quote, from the	02:40:46p
21	patent outstanding properties attributable to the	02:40:49p
22	specific properties of the dissimilar	02:40:52p
23	fiber-forming materials which make up the braided	02:40:55p
24	yarns.	02:40:57p
25	Q. Yeah, I want -- I just want to know	02:41:00p

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1 at the time I must have had that, the 3-43 to	02:43:13p
2 3-48.	02:43:17p
3 Q. Okay. Column 3, Lines --	02:43:17p
4 A. Column 3, Line 43 to 48.	02:43:20p
5 Q. Just so the record is clear, you're	02:43:23p
6 talking about Column 3, Lines 43 to 48?	02:43:24p
7 A. That is correct.	02:43:28p
8 Q. Is there anything in Column 3, Lines	02:43:28p
9 43 to 48, which is discussing the specific	02:43:30p
10 materials which you have from group A?	02:43:33p
11 A. Not that I can see.	02:43:52p
12 Q. Now, in coming to your opinion on the	02:43:53p
13 function --	02:43:56p
14 A. Yes.	02:43:57p
15 Q. -- for purposes of the doctrine of	02:43:57p
16 equivalents --	02:43:59p
17 A. Right.	02:44:00p
18 Q. -- did you consider the prosecution	02:44:00p
19 history of the '446 patent?	02:44:02p
20 A. Not -- not in any meaningful way, no.	02:44:05p
21 Q. What do you mean when you say	02:44:08p
22 meaningful?	02:44:09p
23 A. I didn't -- the answer is no.	02:44:10p
24 Q. Did you -- okay.	02:44:12p
25 A. I had access to the document, but I	02:44:13p

	Page 289
1 never looked at it.	02:44:16p
2 Q. Okay. Did you -- do you have any	02:44:16p
3 understanding of what the claims of the '446	02:44:19p
4 patent were as the patent application was	02:44:21p
5 originally filed?	02:44:26p
6 A. No.	02:44:27p
7 Q. Have you studied as to whether there	02:44:28p
8 were any amendments to the claims --	02:44:31p
9 A. No.	02:44:33p
10 Q. -- in the prosecution history?	02:44:33p
11 A. No.	02:44:35p
12 Q. Okay. Do you think that understanding	02:44:35p
13 the prosecution history in any amendments to the	02:44:39p
14 claims is important for understanding the	02:44:43p
15 function of limitation A?	02:44:46p
16 A. Not in an infringement situation, no.	02:44:53p
17 Q. Okay. You would agree with me that	02:44:59p
18 limitation A that we're discussing requires that	02:45:06p
19 the material be one of the specified listed	02:45:12p
20 materials to literally meet that limitation,	02:45:16p
21 correct?	02:45:20p
22 A. To literally meet it?	02:45:20p
23 Q. Yes.	02:45:22p
24 A. Yes.	02:45:22p
25 Q. Okay. Now, let me refer your	02:45:27p

	Page 290
1 attention to Paragraph 56 of your report.	02:45:55p
2 MR. BONELLA: The first report.	02:46:00p
3 MR. SABER: Yes, we're in the	02:46:01p
4 first report.	02:46:02p
5 BY MR. SABER:	02:46:02p
6 Q. On Page 21.	02:46:02p
7 A. Okay.	02:46:03p
8 Q. And you refer to the testimony of	02:46:04p
9 Mr. Hallet in that paragraph?	02:46:11p
10 A. Yes. Excuse me. Yes.	02:46:13p
11 Q. I'm sorry.	02:46:15p
12 A. Sorry.	02:46:16p
13 Q. And you refer to the testimony of	02:46:17p
14 Mr. Hallet that in the development of FiberWire	02:46:21p
15 he had constructed a 100 percent homogeneous	02:46:25p
16 ultra high molecular weight PE braid but Arthrex	02:46:29p
17 had requested a less stiff braid?	02:46:32p
18 A. That's what I write, yes.	02:46:36p
19 Q. Okay. Why did you rely upon that	02:46:39p
20 testimony? Or let me just and then the next	02:46:40p
21 sentence is, Mr. Hallet then made a heterogeneous	02:46:45p
22 braid of ultra high molecular weight polyethylene	02:46:48p
23 and PET to get the strength of ultra high	02:46:50p
24 molecular weight PET and the flexibility of PET?	02:46:53p
25 A. Yes.	02:46:57p

		Page 300
1	A. PET has a lower tensile modulus and	02:56:30p
2	can affect the tensile stiffness -- I mean, the	02:56:33p
3	bending stiffness in a positive fashion.	02:56:36p
4	Q. Do you mean make it easier to bend?	02:56:39p
5	A. Easier to bend.	02:56:41p
6	Q. Right. And --	02:56:42p
7	A. And easier to hold a knot.	02:56:43p
8	Q. Am I correct that adding the PET to	02:56:46p
9	the ultra high molecular weight braid made the	02:56:51p
10	braid easier to bend?	02:56:55p
11	A. That's what people have said, yes.	02:56:58p
12	Q. Do you believe that to be true?	02:57:00p
13	A. I believe that because it has a lower	02:57:03p
14	tensile modulus, it could make it easier to bend,	02:57:07p
15	that's correct. Modulus, M-O-D-U-L-U-S.	02:57:12p
16	Q. Would you expect that adding the PET	02:57:15p
17	would make the braid easier to bend?	02:57:21p
18	A. Adding or substituting?	02:57:23p
19	Q. Adding -- well, going from an all	02:57:24p
20	ultra high molecular weight PE braid --	02:57:30p
21	A. Right.	02:57:33p
22	Q. -- to a heterogeneous braid of the	02:57:34p
23	combination of ultra high molecular weight PE and	02:57:37p
24	PET would make the braid easier to bend; is that	02:57:40p
25	what your expectation is?	02:57:45p

		Page 301
1	A. In the context of this invention or in	02:57:46p
2	general?	02:57:49p
3	Q. In the context of this invention.	02:57:49p
4	A. In the context of this invention, yes.	02:57:51p
5	Q. Okay. In the context of this	02:57:54p
6	invention, is it your opinion that the ultra high	02:57:55p
7	molecular weight PE braid alone was not easy to	02:58:00p
8	bend?	02:58:05p
9	A. That it was -- it was -- I'm going by	02:58:06p
10	what Mr. Hallet testified, he said Arthrex	02:58:12p
11	requested a less stiff braid, so he went to a	02:58:14p
12	combination, a tailored combination, yes.	02:58:16p
13	Q. So that and would that be your	02:58:18p
14	expectation?	02:58:20p
15	A. That's what I would do.	02:58:20p
16	Q. In the context of this invention?	02:58:21p
17	A. In the context of this invention.	02:58:23p
18	Q. You would expect that the ultra high	02:58:24p
19	molecular weight braid would be -- would not be	02:58:26p
20	easy to bend?	02:58:29p
21	A. Right.	02:58:30p
22	Q. Okay.	02:58:31p
23	A. And he solved the problem by going to	02:58:31p
24	what's the novel and basic characteristics of our	02:58:36p
25	invention. The '446, it's not mine.	02:58:43p

Deposition of:
Dr. David S. Brokstein, Vol. II

July 27, 2006

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1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

ORIGINAL

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13

14 DAY 2 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 27, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

1 A. It is my opinion that if the coating

10:24:09a

2 in some miraculous way made those materials not

10:24:11a

3 yarns anymore and they were no -- they were not

10:24:15a

4 dissimilar anymore, that that would be a change.

10:24:17a

5 If all of a sudden what was once a set of two

10:24:22a

6 dissimilar yarns miraculously became, for

10:24:26a

7 instance, a monofilament, that would be a change,

10:24:29a

8 yeah.

10:24:31a

9 Q. And that would affect the basic and

10:24:32a

10 novel characteristics?

10:24:33a

11 A. If the basic and novel characteristics

10:24:34a

12 are two dissimilar yarns, yes, and all of a

10:24:35a

13 sudden there weren't yarns in there anymore, it

10:24:38a

14 was some new material that was -- that we don't

10:24:41a

15 know about.

10:24:43a

16 Q. Or the yarns were the same yarns, made

10:24:44a

17 the yarns into the same yarns?

10:24:46a

18 A. If they were not dissimilar, right.

10:24:48a

19 Q. Right. So is it your opinion that if

10:24:49a

20 the coating does not -- does not achieve the goal

10:24:54a

21 that you just described, then it does not affect

10:25:00a

22 the basic and novel characteristics of the

10:25:02a

23 invention as Dr. Mukherjee defines it?

10:25:05a

24 A. Can you repeat the question.

10:25:07a

25 Q. Yeah, let me try and rephrase it.

10:25:08a

	Page 400	
1	Is it your opinion that the	10:25:12a
2	coating -- if the coating does not transform	10:25:15a
3	the braided material into another structure,	10:25:20a
4	would you -- let me ask it this way. What do	10:25:24a
5	you mean when you say transform the braided	10:25:27a
6	FiberWire materials into another structure?	10:25:30a
7	A. What do I mean?	10:25:32a
8	Q. Yes.	10:25:33a
9	A. I mean it's not dissimilar yarns	10:25:34a
10	anymore, that would be an example of what I	10:25:36a
11	mean. That all of a sudden you had a set from A,	10:25:38a
12	a set from B and now it was some magical	10:25:41a
13	structure that wasn't yarns, it wasn't two sets,	10:25:45a
14	they were all the same, that would be a	10:25:48a
15	transformation.	10:25:50a
16	Q. Okay.	10:25:52a
17	A. It would be alchemy, but it would be a	10:25:52a
18	transformation.	10:25:56a
19	Q. Okay. If that transformation doesn't	10:25:56a
20	occur by the coating, then is it your opinion	10:25:58a
21	that the coating doesn't affect the basic and	10:26:01a
22	novel characteristics of the invention?	10:26:02a
23	MR. BONELLA: Objection.	10:26:04a
24	THE WITNESS: That's not what I	10:26:04a
25	said.	10:26:05a